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HEYER, DENNIS	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,698	HELLERBRAND ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/27/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Acknowledgement is made of Applicant's remarks and amendments filed January 27, 2010. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are currently pending.

Withdrawn Rejections

Claim rejections – 35 USC § 103

The rejection of claims 1, 4, 6, 8, 11 – 12 and 16 – 17 under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 in view of Klokkers-Bethke *et al.* in US patent 5,335,769 is withdrawn in response to Applicant's arguments.

The rejection of Claims 9, 13, 48 and 52 – 53 under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 in view of Klokkers-Bethke *et al.* in US patent 5,335,769, as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and

further in view of Kohnert *et al.* in WO 2003/043673 is withdrawn in response to Applicant's arguments.

The rejection of Claim 15 under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 in view of Klokkers-Bethke *et al.* in US patent 5,335,769, as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Lee *et al.* in US patent 5,571,523 is withdrawn in response to Applicant's arguments.

The rejection of Claim 51 under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 in view of Klokkers-Bethke *et al.* in US patent 5,335,769, as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Gao *et al.* in US patent 6,113,993 is withdrawn in response to Applicant's arguments.

Response to Arguments

Applicant's arguments filed October 13, 2009 with respect to the rejections under 35 U.S.C 103(a) have been fully considered and are found to be persuasive. Applicant has persuasively argued that the applied references do not teach the process of isothermal drying recited in step (d) of amended Claim 1. Applicant argues that the Examiner has misconstrued isothermal drying with the lyophilization method taught by Klokkers-Bethke and that the two methods are different processes. Accordingly, a new ground of rejection is presented below.

New Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation in which step (b) "providing a solution of the coating substance", can be reversed with step (c) "inserting the device into the solution of the coating substance". It is unclear to the Examiner how one can insert a device into a solution (step c) prior to "providing" said solution (step b). Herein and for the purposes of examination on the merits, with respect to the prior art, the Examiner will consider the embodiment recited in Claim 1 in which step (b) precedes step (c).

Note that Claims 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53, which depend from Claim 1, are also rejected as indefinite under 35 U.S.C. 112, second paragraph.

Claim Rejections – 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the method of Claim 1 recites a limitation in which step (b) "providing a solution of the coating substance", can be reversed with step (c) "inserting the device into the solution of the coating substance". It is unclear how one can insert a device into a solution (step c) prior to "providing" said solution (step b). This is an Enablement Rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561-1562, 27 USPQ2d 1510, 1513 (Fed.Cir.1993). Explaining what is meant by "undue experimentation", the Federal Circuit has stated that:

> The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance, with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.PPGv.Guardian,75 F.3d 1558, 1564 (Fed.Cir.1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands', 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing Exparte Forman, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108,427 F.2d 833,839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

The Wands factors have all been considered. As the nature of the invention, 'inserting a device into a solution before the solution is provided', is unclear, it would be unpredictable as to how one would carry out such a step. Regarding the state of the art, as it is unclear how such a device may be coated, absent the presence of a coating solution, the relative skill of one in the art to do so would necessarily be very high. There are no working examples provided in the specification in which the device is coated prior to providing the coating solution. This is undue experimentation given the limited guidance and direction provided by Applicants.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Note that Claims 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53, which depend from Claim 1, are also rejected for lack of enablement under 35 U.S.C. 112, first paragraph.

Claim rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8, 11 – 12 and 16 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11,

2004, published: February 24, 2005; previously cited in the Office Action mailed November 27, 2009) in view of Talalay in US patent 4,063,367 (published: December 20, 1977).

Song teaches a medical device comprising a substrate, a therapeutic agent containing region over the substrate which comprises a therapeutic agent an antioxidant (a coating) as well as methods of making said coated devices (Abstract)

Song teaches providing a solution comprising a solvent, a therapeutic agent and an antioxidant, contacting the solution with a medical device substrate and then removing the solvent from the solution to form a therapeutic-agent-containing region (Abstract). Song teaches 'dipping techniques' (equivalent to inserting the device into the solution) as a preferred solvent-based technique for contacting the device with a solution (instant Claim 1, step c) Song teaches the solution contacting the medical device substrate comprises a therapeutic agent (a therapeutic substance; Abstract; instant Claim 4).

Instant Claim 6 is drawn to immobilization of the pharmaceutically active substance to an inorganic or organic bioresorbable material. Song teaches that the process of contacting the substrate (the previously formed polymer layer) with a solution containing a therapeutic agent (pharmaceutically active substance) results in said agent being "imbibed by the polymer". One of ordinary skill would reasonably construe the process of "imbibing" (defined as: to take in, absorb) to meet the limitation of 'immobilized' as defined in paragraph [0053] of the instant specification. Song also

teaches that the imbibing (immobilization) may occur within a bioresorbable material including polypeptide biopolymers coatings (paragraph [0039]).

Song teaches the solution contacting the medical device comprises non-active ingredients, specifically, a polystyrene-polyisobutylene block copolymer (page 13, Example 3, paragraph [0050]; instant Claim 8). Song teaches the solution contacting the medical device is an organic solvent, tetrahydrofuran (page 13, Example 3, paragraph [0050]; instant Claim 12). Song teaches the solution contacting the medical device contains an antioxidant, said antioxidant comprising BHT, BHA or tocopherol (Abstract, step a (iii), paragraph [0009], see also, page 13, Example, paragraph [0050]; instant Claim 14). Song teaches that the medical device may be a stent (page 13, Example 3, paragraph [0050]) and that the medical device includes any coated substrate which can comprise, for example, metal (page 3 – 4, paragraph [0020]) (instant Claims 16 and 17).

Claim 1, step (d) recites the limitation that the device is coated by “starting isothermal drying of the device while the device remains held within the solution held within the container, thereby removing the volatile components from the solution of the coating substance".

Song teaches the step of drying a coated medical device in an oven but does not expressly teach the process of isothermal drying as recited in instant Claim 1, step (d), or the limitation of instant Claim 11, wherein the container from which the solvent is removed becomes the packaging container for the device.

Talalay teaches a method for drying liquid contained in a container comprising a biologically active liquid solid composite comprising the step of passing a stream of dry

air over said container in order to evaporate the liquid from said container (Claims 1 and 3). Talalay does not use the term 'isothermal drying', however, Talalay teaches a process in which the temperature is held constant (column 3, lines 56 – 58) and thus the drying process of Talalay is considered to fall within the scope of the process of 'isothermal drying' disclosed on page 20, lines 7 - 25 of the present specification. Tally teaches the containers are subsequently subjected to a vacuum to complete the drying operation (removal of liquid), filled with an inert gas and then sealed (column 2, lines 2 – 7; see also Claims 3 and 4). Talalay teaches that the process of drying the biologically active material and sealing the receptacles ensures a long shelf life (column 2, lines 10 – 13). Talalay teaches that the vacuum step of the process removes residual moisture from the containers as well as oxygen and airborne contaminants. Accordingly, one of ordinary skill would have recognized that the drying process of Talalay teaches a container that becomes the packaging container for the solid material, as recited in instant Claim 11.

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the drying method for the coated medical device of Song using the isothermal drying process taught by Talalay wherein the container becomes the packaging container for the device . One would have been motivated to do so because Talalay teaches the method allows one to seal the receptacle (container) following removal of moisture (liquid) and thus ensure a longer shelf life.

Further, one would have been motivated to remove volatile components from the coated medical device of Song by carrying out the isothermal drying method taught by

Talalay because Song teaches that it may be beneficial to maintain a therapeutic agent coated onto a medical device in a non-oxidizing environment during the course of its formation (page 12, paragraph [0046] and [0047]) and, that subsequent to it's formation, it may be beneficial to place the coated medical device into packaging that has been evacuated or into which an inert gas has been introduced in order to maintain a non-oxidizing environment (paragraph [0047]). Accordingly, one would have been motivated to modify the drying method of Song with the isothermal drying method of Talalay in which the container becomes the packaging container for the device because Talalay teaches said method extends the shelf life of a therapeutic agent and provides an inert (oxygen-free and thus anti-oxidizing) environment.

Claims 9, 13, 48 and 52 – 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) in view of Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Kohnert *et al.* in WO 2003/043673 (publication date: May 30, 2003; previously cited in the Office Action mailed November 27, 2009).

As noted in the 103(a) rejection above, the combination of Song and Talalay renders obvious the method recited in instant Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17.

Song in combination with Talalay do not teach a coating substance comprising calcium phosphates (instant Claim 9), or the device being calcium phosphate or β-

tricalcium phosphate (instant Claims 52 – 53). The references also do not teach an acidic aqueous contacting solution (instant Claim 13), or that the method of instant Claim 1 provides a homogeneous distribution of the coating on the device (instant Claim 48).

Kohnert teaches devices having osteoconductive and osteoinductive properties (Title) comprising a carrier containing calcium phosphate wherein said carrier is homogeneously coated with protein (Abstract). Kohnert teaches a method for preparing said devices comprising providing a solution comprising an osteoinductive protein and a buffer and contacting the solution with a carrier containing calcium phosphate.

Kohnert teaches that the contacting solution comprises a carrier containing calcium phosphate (page 6, 3rd paragraph; instant Claim 9). Kohnert teaches that the device may be made of calcium phosphate or β-tricalcium phosphate (Claim 11, instant Claims 52 and 53). Kohnert teaches that the contacting solution comprises a buffer, and that, preferably, the preferred pH is between 4 and 6 (page 8, paragraphs 3 and 4), which meets the limitation of the instant Claim that the contacting solution be an aqueous acidic solution (instant Claim 13).

Instant Claim 48 is drawn to a homogeneous distribution of the coating on the device. Kohnert teaches a method that provides a homogeneous coating on the surface of the device (page 6, paragraph 3 to page 7 paragraph 1, in particular step (c)) and teaches that an advantage of the present invention is the homogeneous coating which is achieved during the coating process (page 7, paragraph 4).

One would have been motivated to modify the method of coating the device of Song and Talalay, when the solution is an acid aqueous solution (preferably pH 4 - 6) because Kohnert teaches that said pH ranges prevent the precipitation of the bone morphogenic member protein (BMP) family member, GDF-5, from solution and insures the device achieves a homogeneous coating (page 7, paragraph 3 and 4) as nonhomogeneous coatings can lead to decreased osteoinductive properties (page 6, 2nd paragraph). Therefore, Kohnert provides specific motivation to optimize the nature of the coating solution (from an organic solvent to an aqueous acidic solution at pH 4 – 6) of Song by teaching that the protein-derived therapeutic agents taught by Song, which include BMP protein (Song, paragraph [0033]), will remain in solution at an aqueous solution at pH 4 – 6.

One would have been motivated to modify the method of coated a medical device rendered obvious by the combination of Song and Talalay with a bioresorbable material such as calcium phosphate and β-tricalcium phosphate because Kohnert teaches that said materials are effective bone-replacement materials (page 1, paragraph 2) and thus are art-recognized as components of medical devices.

Thus it would have been *prima facie* obvious to one of ordinary skill in the art, to modify the method of Song and Talalay with the teachings of Kohnert, at the time the invention was made, to arrive at the instantly claimed, homogeneously coated medical device with a predictable and reasonable expectation of success.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24,

2005) and Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Lee *et al.* in US patent 5,571,523; published November 5, 1996; previously cited in the Office Action mailed November 27, 2009)

As noted in the 103(a) rejections above, Song in combination with Talaly renders obvious the method of instant Claim 1. The references render obvious that the solution contacting the medical device comprises an antioxidant (such as BHT, BHA or tocopherol, instant Claim 14), but does not expressly teach methionine as the antioxidant.

Regarding instant Claim 15, Lee *et al.* teach a method for inhibiting arteriosclerosis by contacting an artery with an apoptosis-inducing amount of an antioxidant (Abstract) in which methionine is a preferred antioxidant (column 1, lines 37 – 43, Claim 7). Lee teaches that one means for locally delivering the antioxidant is by providing (coating) the antioxidant on the surface of a vascular catheter (a medical device) which contact the wall of a blood vessel (column 1, lines 64 – 67). Thus, it would have been *prima facie* obvious to one skilled in the art, at the time the invention was made, to modify the method rendered obvious over Song and Talalay and use methionine as an antioxidant in place of tocopherol, BHA or BHT on a coated medical device, such as a stent or catheter. One would have been motivated to do so because methionine is effective at inhibiting arteriosclerosis and has been taught by Lee that a means of delivering methionine to a blood vessel is *via* an implantable medical device.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) and Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Gao *et al.* in US patent 6,113,993 (published: September 5, 2000; previously cited in the Office Action mailed November 27, 2009).

As noted in the 103(a) rejection above, Song in combination with Talalay render obvious the method of instant Claim 1. Song in combination with Talalay render obvious a method for coating implantable medical devices in which the coated substrate comprises metal (paragraph [0020]) but do not expressly teach a device made of titanium or a titanium alloy as recited in instant Claim 51.

Gao teaches a method of coating an implant with a calcium phosphate compound on a titanium substrate (Abstract). Gao teaches that orthopaedic implants are commonly made of titanium alloy because of its corrosion resistance to body fluids. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to adapt the method of coating a medical device rendered obvious over Song and Talalay to a device made of titanium. One would have been motivated to do so because implants are commonly made of titanium alloys to gain the benefit of their corrosion resistance to body fluids.

Conclusion

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PADMANABHAN SREENIVASAN can be reached at (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/Timothy P Thomas/
Examiner, Art Unit 1628